



YOUR GUARANTEE OF EXCELLENCE

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K063716

510(k) Summary
Page 1 of 2

December 20, 2007

Owner's Name, Address, Phone and FAX: See the above letterhead

Contact Person: Michael Bono, President

510(k) Number: K063716

DEC 28 2007

Trade Name: *AeroSol*TM Radioaerosol System

Common Name: Nebulizer / Aerosolizer

Classification Name: Nebulizer (Direct Patient Interface) [21CFR868.5630]

Product Code: CAF

Predicate Device: CIS-US (1219718) Aerotech Aerosol Delivery System (K873930 licensed from Cadema Medical Products) and AMICI Xenon System (K865084)

Device Description: The *AeroSol*TM Radioaerosol System generates and administers a fine droplet aerosol to the breathing areas of the lungs for diagnostic imaging. It has an injection site, a nebulizer, aerosol conduit, aerosol trapping and is manufactured of materials and components used in previously cleared 510(k) devices.

Indications for Use: The *AeroSol*TM Radioaerosol System is intended to deliver an aerosol of diagnostic nuclear medicine to the lung for imaging.

Patient Population: For patients undergoing diagnostic nuclear lung ventilation imaging.

Environment of Use: Hospitals or settings where nuclear medicine clinical testing is performed.

510(k) Summary

Page 2 of 2

Specification	<p align="center">Predicate CIS-US AeroTech System (K873930) AMICI Xenon System (K865084)</p>	<p align="center">Proposed AeroSol™ System (K063716)</p>
Indications for use	To diagnose or rule out lung ventilation (airways) versus lung perfusion (blood supply) diseases in patients with breathing difficulties.	The AeroSol™ Radioaerosol System is intended to deliver an aerosol of diagnostic nuclear medicine to the lung for imaging.
Patient populations	For patients with breathing difficulties suspected of airways diseases.	For patients undergoing diagnostic nuclear lung ventilation imaging in a hospital or settings where nuclear medicine clinical testing is performed.
Environment of use	Hospitals or settings where nuclear medicine clinical testing is performed	Hospitals or settings where nuclear medicine clinical testing is performed
Performance	Nebulize radioaerosols	Nebulize radioaerosols
Nebulizer Performance tested via Malvern Laser Defraction	Yes	Yes
Circuit with conduits, valves, nebulizer, mouthpieces, and various adapters and connectors and aerosol trapping filter	Yes AMICI Xenon System (K865084)	Yes
Materials – PVC, LDPE, K-Resin, Bromobutyl etc.	Yes AMICI Xenon System (K865084)	Yes

Differences Between Other Legally Marketed Predicate Devices: The proposed device is viewed as substantially equivalent to the predicate devices, K873930 and K865084. There are no significant differences that affect the safety, use or effectiveness of the intended device as compared to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 28 2007

Mr. Michael Bono
President
AMICI, Incorporated
518 Vincent Street
Spring City, Pennsylvania 19475

Re: K063716
Trade/Device Name: AeroSol™ Radioaerosol System
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: December 13, 2007
Received: December 14, 2007

Dear Mr. Bono:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

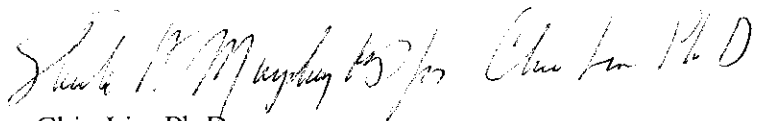
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

Page 1 of 1

510(k) Number: **K063716**

Device Name: **AeroSol™ Radioaerosol System**

Indications for Use:

The **AeroSol™** Radioaerosol System is intended to deliver an aerosol of diagnostic nuclear medicine to the lung for imaging. The device is intended for patients undergoing diagnostic nuclear lung ventilation imaging in a hospital or settings where nuclear medicine clinical testing is performed.

Prescription Use (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K063716